

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

CYTOLOGIX CORPORATION,

Plaintiff,

v.

VENTANA MEDICAL SYSTEMS, INC.,

Defendant.

Civil Action No. 04-11783 (RWZ)

**CYTOLOGIX CORPORATION’S STATEMENT OF MATERIAL FACTS TO WHICH
THERE IS NO GENUINE DISPUTE**

1. CytoLogix Corporation (“CytoLogix”) is the owner by assignment of United States Patent No. 6,541,261, the patent-in-suit (“the ‘261 patent”). (Zeliger Ex. 1, ‘261 Patent).

2. Ventana Medical Systems, Inc. (“Ventana”) manufactures, sells and actually uses its BenchMark XT and BenchMark LT instruments. (Zeliger Ex. 2 at 58:21-25, Zeliger Exs. 9-11).

3. These instruments differ only in the number of slides that they hold. (“I don’t believe that there’s any other differences, other than capacity.”) (Zeliger Ex. 2 at 45:20-21).

4. Ventana previously manufactured and sold its BenchMark instrument. (Zeliger Ex. 2).

5. The BenchMark has been adjudicated to infringe United States Patents 6,180,061 and 6,183,693, which patents were found to be valid. (*CytoLogix Corp. v. Ventana Medical Systems, Inc.*, 424 F.3d 1168 (Fed. Cir. 2005)).

6. The slide carousel in the BenchMark rotated. (Zeliger Ex. 9 at 2 (VM000011), 3 (VM000012) and 4 (VM000013)).

7. The liquid dispenser in the BenchMark XT and BenchMark LT rotate. (Zeliger Ex. 9 at 2 (VM000011), 3 (VM000012) and 4 (VM000013)).

8. The BenchMark and the BenchMark XT, BenchMark LT are otherwise very similar. (Zeliger Ex. 2 at 45:20-21).

9. The '261 patent concerns automated instruments that replace manual slide staining techniques. (Zeliger Ex. 1).

10. The '261 patent is in the same family as CytoLogix's '693 patent. (Zeliger Ex. 1).

11. The '261 patent claims an improved slide staining method, which runs multiple procedures to numerous samples mounted on slides, concurrently. (Zeliger Ex. 1 at 1:66-27, 2:1-10.)

12. Unlike slide stainers existing in the prior art, the invention claimed by the '261 patent allows for individual slides to be heated to different temperatures. (Zeliger Ex. 1. at 2:5-10.)

13. Specifically, the '261 patent discloses and claims a way "to heat slides to different temperatures, independently of the temperatures of other slides." (Zeliger Ex. 1 at 2:7-9.)

14. In addition, the invention allows for "complete random access, i.e., any reagent to any slide in any sequence." (Zeliger Ex. 1 at 7:41-43.)

15. Such "random access" is advantageous because it allows the instrument run different staining protocols on different samples, all at the same time.

As the '261 patent explains:

Tissue sections or cellular monolayers are commonly examined by microscopic examination, for both research and clinical diagnostic purposes. Thin tissue sections or cellular preparations are commonly 1-10 microns thick, and are nearly transparent if untreated. In order to visualize various histologic features, a wide array of staining procedures have been developed over the years that highlight various cellular or extracellular components of the tissues. Histochemical stains, also commonly termed "special stains," employ chemical reactions to color various chemical moieties. Immunohistochemical stains employ antibodies as probes to color specific proteins, commonly via enzymatic deposition of a colored precipitate. ***Each of these histochemical and immunohistochemical stains requires the addition and removal of reagents in a defined sequence for specific time periods, at defined temperatures. Therefore, a need arises for a slide***

stainer that can perform a diversity of stains simultaneously under computer control, as specified by the technologist.

(Zeliger Ex. 1 at 1: 12-30, emphasis added.).

16. The '261 patent has seven claims, six of which are dependent. (Zeliger Ex. 1)

Claims 1 and 2 are asserted in this case.

17. Claim 1 is an independent claim:

1. A method of processing samples mounted on microscope slides comprising:
placing two or more microscope slides on a platform;
providing heating elements being under independent electronic control, and thereby capable of heating some slides to a different temperature than other slides;
moving the platform and a liquid dispenser relative to each other;
dispensing liquid from the dispenser onto the slides;
and
on the platform, heating one slide to a different temperature than a second slide.

(Zeliger Ex. 1 at 12:14-26.)

18. Claim 2 is a dependent claim:

A method of processing samples mounted on microscope slides as claimed in claim 1, wherein each heating element heats only one slide.

(Zeliger Ex. 1 at 12:26-28.)

19. The specification of the '261 patent explains the importance of indexing and independent slide heating: "Since various procedures require heat at different times to enhance the rate of chemical reaction, a means has been developed to heat slides to different temperatures, independently of the temperatures of other slides." (Zeliger Ex. 1 at 2:5-9.)

20. The specification provides examples of these various procedures:

Variables in these protocols can include the particular reagent used on the tissue sample, the time that the tissue sample is allowed to react with the reagent, whether the tissue sample is then heated, the rinse that is then used to wash the reagent away, followed by the subsequent removal of the rinse and reagent to allow subsequent exposure to a possibly different reagent.

(Zeliger Ex. 1 at 7:35-41.)

21. A necessary component is that slides be aligned with the dispenser:

It is possible to dispense from any of a plurality of cartridge pumps by rotating the reagent rotor so as to align a desired cartridge pump 46 with the hammer 26. This provides the capability of dispensing precisely measured amounts of reagent to any slide positioned underneath the cartridge pump 46 adjacent to actuator 26.

(Zeliger Ex. 1 at 5:29-35.)

22. Two examples of achieving this alignment are described, wherein the slides rotate to the liquid dispenser, but nothing in the specification or this embodiment conflicts with the concept of relative motion. Indeed the specification even notes that the examples should not be considered exclusive:

While this invention has been particularly shown and described with references to preferred embodiments thereof, it will be understood by those skilled in the art that various changes in form and details may be made therein without departing from the spirit and scope of the invention as defined by the appended claims.

(Zeliger Ex. 1 at 12:3-8.)

23. The original claims in the application for the '261 patent referred to a "moving platform." (Zeliger Ex. 3 at 21 (claims 1, 3, 4).)

24. Throughout several amendments, the amended claims continued to refer to a "moving platform." (Zeliger Ex. 4 and Zeliger Ex. 5 at 2-3.)

25. However, following an interview with the patent examiner, the applicant voluntarily made a broadening amendment and removed the "moving platform" limitation from all claims. The following are "marked up" versions of these claims showing the changes:

1. (Thrice Amended) A method of processing samples mounted on microscope slides as claimed in claim 8 further comprising:
[placing two or more microscope slides on a moving platform, the moving platform having heating elements thereon to heat said slides;]
communicating data from a computer not located on the moving platform to electronic circuitry mounted on the moving platform; and
processing the data in the electronic circuitry on the moving platform and supplying from the electronic circuitry on the moving platform, amounts of electrical power to the heating elements dependent on the data, to heat one of the slides to a different temperature than a second one of the slides.

5. (Twice Amended) A method of processing samples on microscope slides as claimed in claim 8 further comprising:
[positioning a plurality of microscope slides bearing biologic samples on a moving platform, said moving platform having a plurality of heating elements controllable to individual temperatures and electronic circuitry thereon;]
providing a computer comprising a user interface through which a desired temperature for each microscope slide is specified, said user interface being mounted off of the moving platform;
sending data from the computer to the electronic circuitry on the moving platform over a group of conductors, the number of conductors in said group of conductors being less than the number of heating elements controllable to individual temperatures; and
processing the data in the electronic circuitry on the moving platform, and supplying electrical power to the heating elements from the electronic circuitry on the moving platform.

6. (Amended) A method of processing samples mounted on microscope slides comprising:
placing two or more microscope slides on a [moving] platform;
providing heating elements capable of heating said slides, said heating elements being
under independent electronic control and thereby capable of heating some slides to a different temperature than other slides; [and]
moving the platform and a liquid dispenser relative to each other;
dispensing liquid from the dispenser onto the slides; and
on the [moving] platform, heating one slide to a different temperature than a second slide.

8. (Amended) A method of processing samples mounted on microscope slides as claimed in claim 6, wherein the platform is a moving platform [is] capable of indexing slides adjacent to a stationary liquid dispensing location.

(Zeliger Ex. 6 at 1-2.).

26. The applicant expressly noted this change to the to the examiner:

Amended independent claim 6 recites independent temperature control of slides in a system in which ***a liquid dispenser and a slide supporting platform are moved relative to each other in order to dispense liquid on the slide***. None of the prior art, alone or in combination, teaches such a system.

(Zeliger Ex. 6 at 4-5 (emphasis added).)

27. The examiner explained that the key to the invention was staining capability coupled with independent and individual slide temperature control:

* Applicant asserted combination of automated staining of automated individual & independent slide Temp. control was non-obvious. Exmr. indicated such combination was not presently claimed. Applicant's assertion that separate & distinct Temp. controls, i.e. heating to different temperature, in the primary '114 reference would not have been considered purposeful nor desired in the environment of that disclosure would be considered as 2nd evidence on non-obviousness when filed.

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

Examiner's signature, if required

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(Zeliger Ex. 7.)

28. The examiner later explained his rationale—the inventiveness of “the capability of heating simultaneously to different temperatures”—in his “statement of reasons for allowance”:

Applicant's response filed 10-04-02 obviates the rejections set out in the last office action. The claims as now amended are directed to methods for processing samples which includes both dispensing of fluids onto moveable sample slides and simultaneously heating different sample slides to different temperatures. The response filed by applicant, including the submitted articles in support of the argument, are in the totality sufficient to establish that *one of ordinary skill in the art viewing the apparatus of the '114 patent, would not have recognized any necessity nor desirability, absent applicant's disclosure, of providing the capability of heating simultaneously to different temperatures.*

(Zeliger Ex. 8 at 2 (emphasis added).)

29. The BenchMark XT processes samples mounted on microscope slides. (Zeliger Ex. 2 at 48:18-20, Zeliger Ex. 9 at 1 (VM000010), 209 (VM000218), Zeliger Ex. 10 at 5 (VM000444)).

30. The BenchMark LT processes samples mounted on microscope slides. (Zeliger Ex. 2 at 48:21-23, Zeliger Ex. 9 at 1 (VM000010), 209 (VM000218) and Zeliger Ex. 10 at 5 (VM000444)).

31. The BenchMark XT holds two or more microscope slides on a platform. (Zeliger Ex. 2 at 48:24-49:1, Zeliger Ex. 10 at 9 (VM000448) and 26 (VM000465)).

32. The BenchMark LT holds two or more microscope slides on a platform. (Zeliger Ex. 2 at 49:2-4, Zeliger Ex. 10 at 9 (VM000448) and 26 (VM000465)).

33. The BenchMark XT contains heating elements that are capable of heating some slides to different temperatures than other slides. (Zeliger Ex. 2 at 51:2-13, Zeliger Ex. 10 at 7 (VM000446)).

34. The BenchMark LT contains heating elements that are capable of heating some slides to different temperatures than other slides. (Zeliger Ex. 2 at 51:2-15, Zeliger Ex. 10 at 7 (VM000446)).

35. The BenchMark XT has heating elements that are under independent electronic control, such that slides can be heated to different temperatures. (Zeliger Ex. 2 at 51:2-13, Zeliger Ex. 10 at 7 (VM000446)).

36. The BenchMark LT has heating elements that are under independent electronic control, such that slides can be heated to different temperatures. (Zeliger Ex. 2 at 51:2-15, Zeliger Ex. 10 at 7 (VM000446)).

37. The liquid dispenser on the BenchMark XT moves relative to the slide sample platform. (Zeliger Ex. 2 at 83:23-25, Zeliger Ex. 9 at 2 (VM000011), 3 (VM000012) and 4 (VM000013), and Zeliger Ex. 11 at 14 (VM000249) and 19 (VM000254)).

38. The liquid dispenser on the BenchMark LT moves relative to the slide sample platform. (Zeliger Ex. 2 at 83:1-3, Zeliger Ex. 9 at 2 (VM000011), 3 (VM000012) and 4 (VM000013), and Zeliger Ex. 11 at 14 (VM000249) and 19 (VM000254)).

39. The BenchMark XT dispenses liquid from the dispenser onto the slides. (Zeliger Ex. 2 at 51:16-19, Zeliger Ex. 11 at 14 (VM000249)).

40. The BenchMark LT dispenses liquid from the dispenser onto the slides. (Zeliger Ex. 2 at 51:20-22, Zeliger Ex. 11 at 14 (VM000249)).

41. The BenchMark XT heats one slide on a platform to a different temperature than another slide. (Zeliger Ex. 2 at 51:23-25, Zeliger Ex. 11 at 68 (VM000303)).

42. The BenchMark LT heats one slide on a platform to a different temperature than another slide. (Zeliger Ex. 2 at 52:1-3, Zeliger Ex. 11 at 68 (VM000303)).

43. In the BenchMark XT, each heating element heats only one slide. (Zeliger Ex. 2 at 52:4-6, Zeliger Ex. 11 at 68 (VM000303)).

44. In the BenchMark LT, each heating element heats only one slide. (Zeliger Ex. 2 at 52:7-9, Zeliger Ex. 11 at 68 (VM000303)).

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Date: November 17, 2005

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CERTIFICATE OF SERVICE

I hereby certify that on the 17th day of November, 2005, a true and correct copy of the foregoing CYTOLOGIX CORPORATION'S STATEMENT OF MATERIAL FACTS TO WHICH THERE IS NO GENUINE DISPUTE was caused to be served on the attorney at the following address as indicated:

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